EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:
1:13-cv-10626-FDS

MDL No. 2419
Master Docket No. 1:13-md-2419-FDS

Honorable F. Dennis Saylor

Second Amended Complaint and Demand for Jury Trial

VILINDA YORK,

Plaintiff,

v.

NEW ENGLAND COMPOUNDING PHARMACY, INC. D/B/A NEW ENGLAND COMPOUNDING CENTER (NECC), AMERIDOSE L.L.C., MEDICAL SALES MANAGEMENT INC., MEDICAL SALES MANAGEMENT SW, INC. GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA INC., D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLARIO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN CHINN AND LIBERTY INDUSTRIES, INC.,

Defendants.
_____/

Plaintiff Vilinda York sues Defendants New England Compounding Pharmacy, Inc., doing business as New England Compounding Center (hereinafter "NECC"), Ameridose L.L.C. (hereinafter "Ameridose"), Medical Sales Management Inc., (hereinafter "MSM"), Medical Sales Management SW, Inc., (hereinafter "MSM-SW"), GDC Properties Management, LLC (hereinafter "GDC"), ARL BIO Pharma Inc., d/b/a Analytical Research Laboratories (hereinafter

"ARL"), and individual Defendants, Barry J. Cadden, Gregory Conigliaro, Lisa Coniglario Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chinn (collectively jointly referred to as the "NECC Related Entities")[1], and Liberty Industries, Inc. (hereinafter "Liberty"), and states as follows:

JURISDICTION, PARTIES & VENUE

1. This is a products liability, fraud, unfair trade practices and negligence action for damages that exceed seventy five thousand dollars ($75,000.00) exclusive of interest, costs, and attorneys' fees.

2. At all times relevant hereto Plaintiff Vilinda York was and is a resident of Marion County, Florida.

3. Defendant NECC was and is a Massachusetts corporation that compounded and manufactured drugs in Framingham, Massachusetts for distribution and sale across the United States, including the State of Florida. The Registered Agent for NECC in Florida is CT Corporation System, 1200 South Pine Island Road, Plantation, FL, 33324. United States Bankruptcy Court Judge Boroff has lifted the bankruptcy stay as to NECC for the limited purpose of allowing Plaintiff to file and serve the instant complaint as to NECC in In Re: New England Compounding Pharmacy, Inc., case number 12-19882-HJB.

4. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts corporation that maintains its principal place of business at 205 Flanders Road, Westborough, Massachusetts. The resident agent for service of process for Ameridose in Florida is the Corporation Company at 30600 Telegraph Road, Ste 2345, Bingham Farms, MI 48025; the registered agent for service of process in Massachusetts is Gregory Conigliaro at 205 Flanders Road in Westborough, Massachusetts.

[1] The NECC Related Entities include NECC itself, as well as other subsidiaries and businesses owned and operated by the principals described herein as the NECC individuals. This pleading intends to delineate between NECC owned and operated parties and Liberty Industries, Inc., and unrelated entity.

5. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation that maintains its principal place of business at 697 Waverly Street in Framingham, Massachusetts; the registered agent for service of process in Massachusetts is Gregory Conigliaro at 697 Waverly Street in Framingham, Massachusetts.

6. Defendant Medical Sales Management SW, Inc. ("MSM-SW") is a Massachusetts corporation that maintains its principal place of business at 701 Waverly Street in Framingham, Massachusetts. The resident agent for service of process for MSM-SW in Florida is the Corporation Company at 30600 Telegraph Road, Suite 2345, Bingham Farms, MI 48025; the registered agent for service of process in Massachusetts is Gregory Conigliaro at 687 Waverly Street in Framingham, Massachusetts. MSM-SW was organized in Massachusetts in December, 2010 and applied to do business in Florida in April, 2012.

7. Defendant GDC Properties Management, LLC ("GDC") is a Massachusetts limited liability company with a principal place of business at 701 Waverly Street, Framingham, Massachusetts. GDC's manager and registered agent is Gregory Conigliaro.

8. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma. The Chief Executive Officer and Registered Agent of ARL is Thomas C. Kupiec.

9. Defendant Barry J. Cadden resides at 13 Manchester Drive, Wrentham, MA. Until recently, he was an owner, President, Head Pharmacist, and Director of Pharmacy at NECC. He oversaw the day to day operations of NECC. Cadden is a founder and Manager of Ameridose and is involved in its day to day operations. Mr. Cadden was the Treasurer and a Director of MSM and MSM-SW.

10. Defendant Lisa Conigliaro Cadden (sometimes referred to as Lisa Cadden, Lisa Conigliaro, or Lisa Cadden Conigliaro) resides at 13 Manchester Drive, Wrentham, MA, and is a board member, Director, and pharmacist at NECC. Lisa Conigliaro Cadden, upon information and belief, was involved in the day to day operations of NECC. Lisa Conigliaro Cadden is a director of MSM-SW. Defendants Barry Cadden and Lisa Conigliaro Cadden are sometimes referred to as the "Cadden Defendants."

11. Defendant Gregory Conigliaro resides at 1 Mountain View Drive, Framingham, MA, and is a principal owner, Treasurer, Secretary, Vice President, and a Director of NECC. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Mr. Conigliaro is a founder and Manager of Ameridose and is involved in its day to day operations, and is Secretary and Director of MSM and MSM-SW. Mr. Conigliaro is the sole manager of GDC.

12. Defendant Douglas Conigliaro resides at 15 Hale Drive, Dedham, MA, and is the President and Director of MSM and MSM-SW. Douglas, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM and MSM-SW.

13. Defendant Carla Conigliaro resides at 2110 Fawsett Road, Winter Park, FL, and is a Director at NECC. Defendants Gregory Conigliaro, Douglas Conigliaro and Carla Conigliaro are sometimes referred to as the "Conigliaro Defendants."

14. Defendant Glenn A. Chin resides at 173 Mechanic Street, Canton, MA, and is an employee and leader at NECC. Chin was present during the state and federal investigations of NECC's premises.

15. Defendant Liberty Industries, Inc., is a Connecticut Corporation that designed and built the "clean rooms" used at NECC. The Principal Address of Liberty Industries, Inc. is 133

Commerce Street, East Berlin, CT, 06023. The Registered Agent of Liberty Industries, Inc. is John J. Nappi, Jr., at 133 Commerce Street, East Berlin, CT, 06023.

16. The NECC Related Entities were authorized to do business and did business in Marion County, Florida. The Individual Defendants controlled and operated the Corporate Defendants that were authorized to do business and did business in Marion County, Florida.

17. This Court has jurisdiction pursuant to 28 U.S.C. § 1332.

18. The Court has personal jurisdiction over Defendants pursuant to Florida's Long-Arm Statute and due process because:

a. Defendants caused injury to Plaintiff that arose out of the acts and omissions that occurred outside of the State of Florida during the relevant period of time, namely, the negligent manufacturing of unreasonably dangerous methylprednisolone acetate (prednisone) that caused personal injury to Plaintiff as set forth herein;

b. Defendants engaged in substantial and not isolated activity within Marion County by marketing, selling, and distributing prednisone and other pharmaceuticals into the State of Florida; and,

c. Defendants committed a tortious act within the State of Florida.

19. Venue is proper in the Middle District of Florida as this Court has personal jurisdiction over Defendants in the Middle District as set forth above and Plaintiff resides in the Middle District. Pursuant to 28 U.S.C. § 1407 and *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998) this matter is appropriate for remand to the Middle District of Florida.

20. At all times relevant hereto Defendants acted by and through their employees, agents, and representatives who were all working within the scope of their employment, agency,

and representative capacity with Defendants and working in furtherance of Defendants' interests.

21. All conditions precedent to the bringing of this action have occurred, been waived, or been otherwise satisfied.

NECC'S RELATED ENTITIES: AMERIDOSE, MSM AND MSM-SW

22. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose, Alaunus and NECC, as well as other Properly Licensed Facilities in the future."

23. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

24. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

25. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

26. At all relevant times, NECC's privacy policy on its website referred to the "Ameridose Privacy Policy."

27. On April 11, 2011, NECC used Ameridose to request certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

28. In 2012, NECC salespersons recommended NECC's "sister company," Ameridose,

for drug compounds that NECC did not have available.

29. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com.

30. MSM acted, at all relevant times, as the sales arm for NECC nationwide, promoting NECC's compounding business at trade shows across the country, calling new and existing customers, and managing NECC's computer operations.

31. MSM printed and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM has stated: "I didn't think there was any difference [between Ameridose and NECC]."

32. MSM-SW acted, at all relevant times, as the sales arm for NECC in Michigan, promoting NECC's compounding business within the State, calling new and existing customers, and making representations about the quality of its products.

33. Through September 2012, both NECC and Ameridose used MSM and MSM-SW for sales and marketing functions.

34. Upon information and belief, there were many other occasions where employees of Ameridose, MSM, and MSM-SW would perform services at the direction of NECC.

35. These relationships, among others, were the result of and establish the fact that Defendants, Ameridose, MSM and MSM-SW are and were organized and operated as the alter ego of NECC for the benefit and advantage of NECC and the Cadden and Conigliaro defendants, and at all times relevant thereto the alter egos exercised dominion and control over NECC. Further, NECC and affiliated companies Ameridose, MSM and MSM-SW have so intermingled each of their business affairs, that all of said corporate Defendants are the alter egos of each other.

36. That the Defendant NECC and affiliated companies, Ameridose, MSM and MSM-SW are in substance the same, and that the Defendant corporations are but the alter egos of each other, acting solely as a device to cause harm or prejudice to the creditors of the corporations.

37. That at all times relevant hereto, NECC and affiliated companies, Ameridose, MSM and MSM-SW were operated jointly, and all such businesses were, and are operated as a joint venture and/or in concert with each other.

NECC RELATED ENTITY: GDC

38. GDC owns the real property and improvements thereon at 685-705 Waverly Street, Framingham, Massachusetts.

39. From 1998 until at least October 2012, GDC leased a portion of the premises at 697 Waverly Street to NECC.

40. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight (8) major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

41. GDC maintained a high degree of control over the premises leased by NECC.

42. GDC knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Place, and GDC knew that this medication was injected into humans and was required to be sterile.

43. GDC knew that the facilities it was leasing to NECC were unsuitable for use as a compounding pharmacy, yet continued to lease said premises to NECC for that purpose.

44. Further, upon information and belief, GDC knew that said premises were deteriorating, increasing the likelihood that NECC's products would be contaminated, yet failed to remedy the defects in the premises that were contributing to that contamination.

45. As a direct and proximate result of GDC's actions and inactions, the steroids being compounded by NECC became contaminated, and injured the Plaintiffs as described herein.

NECC'S RELATED ENTITIES: ARL

46. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

47. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

48. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

49. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. **You should expect nothing less from the testing laboratory you entrust"** (emphasis in original).

50. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's **"[t]esting methods and technologies [are] unparalleled in the market today"** (emphasis in original).

51. With respect to its sterility tests, ARL, on its Internet website, states: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

52. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

53. From May through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about July 3, 2012, NECC sent to ARL two (2) 5ml vials of methylprednisolone acetate from a batch of thousands of vials that came from Lot 06292012@26, which, upon information and belief, had been compounded by NECC on June 29, 2012.

54. On or about July 5 and/or July 6, 2012, ARL sent to NECC a Microbiology Report and Certificate of Analysis dated July 5 and July 6 respectively, which stated that the two (2) vials had been tested on July 3, 5 and 6, 2012.

55. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two (2) 5ml vials of methylprednisolone acetate that NECC sent to ARL and described herein, were "sterile." ARL's

report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

56. Pursuant to the protocols of test method USP 71, sterility testing of methylprednisolone acetate should have been conducted on far more vials from the batch than ARL tested.

57. During the summer of 2012, MSM and MSM-SW sales representatives, on behalf of NECC, distributed copies of the ARL Microbiology Report and Certificate of Analysis concerning the testing of the vials of methylprednisolone acetate from Lot 06292012@26 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

58. Among the customers who received the aforementioned ARL reports was Michigan Pain Specialists, in Brighton, Michigan. The Plaintiff herein were ultimately injected with MPA from NECC lot #06292012@26 by physicians of Michigan Pain Specialists.

59. ARL was well aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

a. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

b. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

c. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

d. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounding products since 1990. Some of these instances had devastating repercussions."

60. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

61. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

62. As a direct result of ARL's actions and inactions as described herein, NECC was not advised that its lots of methylprednisolone acetate were contaminated; NECC continued to compound, market and distribute its drugs, including the contaminated methylprednisolone acetate, and Plaintiff was injected with said drug resulting in the injuries previously alleged.

FACTS GIVING RISE TO CAUSE OF ACTION

63. NECC is what is known as a "compounding pharmacy."

64. A traditional compounding pharmacist is one who combines, mixes or alters ingredients in a medication in response to a physician's prescription to create a medication tailored to the needs of a patient when the medication is not available commercially, such as a drug for a

patient who is allergic or diluted doses for children.

65. Compounding pharmacies were to be exempt from the Food and Drug Administration's ("FDA") enforcement of the Food Drug Cosmetic Act ("FDCA") provided that the drug was compounded for an identified individual patient based on a valid prescription.

66. Being exempt from FDCA and the FDA's authority led to a proliferation of compounding pharmacies over the last 15 years, leaving the compounding pharmacies subject to state oversight.

67. Nonetheless, the FDA exercised discretionary authority to oversee compounding pharmacies at various times.

68. On December 4, 2006, the FDA warned NECC that it considered the drugs NECC was manufacturing to be "new drugs" within the meaning of the FDCA and that the "new drugs" may not be sold into interstate commerce without FDA approval.

69. NECC never obtained FDA approval for the prednisone it compounded and sold to Marion Pain Management Clinic, located in Ocala, Florida, where Plaintiff received injections of the tainted prednisone.

70. On September 21, 2012, the U.S. Centers for Disease Control (hereinafter "CDC") was notified by the Tennessee Department of Health of a patient with the onset of fungal meningitis due to an epidural steroid injection.

71. On September 24, 2012, the Tennessee Department of Health notified the Massachusetts Department of Public Health about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. The Tennessee Department of Health noticed this cluster of cases because of the rarity of fungal meningitis. These patients all received injections of prednisone compounded by NECC.

72. On September 25, 2012, the Massachusetts Department of Health, Board of Registration in Pharmacy, and Bureau of Infectious Diseases convened a multi-agency meeting with the Tennessee Department of Health, the CDC, the FDA, and NECC.

73. On September 26, 2012, the investigation of NECC's facility began. When investigators arrived they found NECC employees cleaning compounding areas and conducting environmental testing. The investigators also detected signs of black decontamination in the compounding areas.

74. A recall of the prednisone from NECC was immediately ordered; however; more than 14,000 people are estimated to have received tainted prednisone from NECC containing funguses that cause spinal meningitis.

75. The Massachusetts Department of Health and FDA identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk" at NECC.

76. The FDA and Massachusetts Department of Health found deplorable conditions at NECC, for example:

a. fungal contamination by microscopic examination of particulate matter taken from a sealed vial of prednisone collected from NECC;

b. "foreign material" in prednisone;

c. "visible black particulate matter" in the prednisone;

d. "greenish black" foreign matter in the prednisone;

e. "white filamentous" material in the prednisone;

f. viable microbial growth in the prednisone;

g. powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned. Residual powder was visually observed, which could lead to contamination of compounded medications;

h. "tacky mats" used to trap dirt, dust, and other potential contaminants from the "clean room[2]" entry were visibly soiled with debris;

i. a leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water;

j. dust and airborne contaminants from an nearby recycling plant were found in the clean room at NECC;

k. temperatures in the clean room fluctuated due to the air conditioning being turned off at night, providing an opportunity for microbial growth;

l. surfaces in the clean room at NECC had reddish-brown substances and "dark, hair like discoloration."

77. Apart from the deplorable physical conditions at NECC, NECC was also found to have distributed at least two of the recalled lots of prednisone *before* receiving results of sterility testing. Moreover, on prednisone that NECC had allegedly tested and reported as sterile, the FDA found microbial growth.

78. The investigation also found that NECC did not follow proper autoclaving sterilization procedure or its own standard operating procedures. NECC systematically failed to

[2] A clean room is a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles and microbes inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary.

keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

79. Investigators found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license. If NECC had been licensed as a manufacturer with the FDA, it would have been subject to additional levels of scrutiny.

80. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

81. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

82. NECC ignored its own environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce "sterile" drugs. At least 38 times the bacterial levels exceeded limits where action was to be taken by NECC, yet NECC took no corrective action.

83. On October 18, 2012, the FDA released definitive laboratory confirmation of the presences of fungal contaminants in sealed vials of prednisone at NECC.

84. Plaintiff Vilinda York received epidural injections of prednisone while being treated for pain at Marion Pain Management Clinic located in Ocala, Florida.

85. Marion Pain Management Clinic purchased the tainted prednisone from Defendant NECC.

86. After receiving the injections, Plaintiff Vilinda York developed symptoms of fungal meningitis. Ms. York was eventually diagnosed with fungal meningitis after a spinal tap was performed and her cerebrospinal fluid was tested.

87. Plaintiff Vilinda York endured a lengthy hospital stay to be treated with high doses of antifungal medications that may cause kidney failure.

88. Complications and risks from meningitis include: brain damage, buildup of fluid between the skull and brain (subdural effusion), hearing loss, hydrocephalus, and seizures.

COUNT I
NEGLIGENCE AGAINST NECC AND NECC'S RELATED ENTITIES (AMERIDOSE, MSM, MSM-SW, ARL, GDC AND THE INDIVIDUAL DEFENDANTS)

89. Plaintiff adopts and restates paragraphs 1-88 as if fully set forth herein.

90. Defendants NECC, Ameridose, MSM, MSM-SW, and the Individual Defendants in addition to Defendants ARL and GDC, owed a duty of reasonable care to Plaintiff to provide a reasonably safe steroid, free from contamination, and to adequately warn of their failure to do the same. Defendants' duty included, but was not limited to:

a. properly designing, compounding and selling its steroids in such a manner as to provide a reasonably safe use of it;

b. properly designing, compounding and selling its steroids in such a manner as to provide a medication that was fit for its intended purposes;

c. properly designing, compounding and selling its steroids to prevent adverse events;

d. adequately warning Plaintiff or the public regarding the likelihood of injury arising out of the use of its steroids, at the time of design, compound and post- compounding but prior to its injection into Plaintiff;

e. adequately warning Plaintiff or the public regarding the likelihood that its steroids could cause adverse effects;

f. properly testing and inspecting its design, testing and production systems of its steroids, before placing them into the stream of commerce;

g. using alternative available production practices that would have prevented the contamination of its steroids without significantly impairing the product;

h. exercising reasonable care in making the design and production choices made by Defendant;

i. adequately testing said compounds to ensure that they were safe for general use;

j. keeping its premises in reasonable repair and suitable for the uses to which they were being put;

k. recalling said steroids in a timely manner;

l. Otherwise exercising reasonable care in the production and manufacture of steroids.

91. As a direct and proximate result of Defendants' acts and omissions, Plaintiff have incurred damages and are entitled to damages as previously alleged.

92. Defendants were negligent and breached their duty of reasonable care to Plaintiff to provide a reasonably safe steroid free of contamination and to adequately warn of their failure to do the same. Defendants' breaches included but were not limited to the following:

a. failure to properly design, compound and sell its steroids in such a manner as to provide a reasonably safe use of it;

b. failure to properly design, compound and sell its steroids in such a manner as to provide a medication that was fit for its intended purposes;

c. failure to properly design, compound and sell its steroids to prevent adverse events;

d. failure to adequately warn Plaintiff or the public regarding the likelihood of injury arising out of the use of its steroids, at the time of design, compound and post- compounding but prior to its injection into Plaintiff;

e. failure to adequately warn Plaintiff or the public regarding the likelihood that its steroids could cause adverse effects;

f. failure to properly test and inspect its design, testing and production systems of its steroids, before placing them into the stream of commerce;

g. failing to use alternative available production practices that would have prevented the contamination of its steroids without significantly impairing the product;

h. failure to exercise reasonable care in making the design and production choices made by Defendant;

i. failing to adequately test said compounds to ensure that they were safe for general use;

j. failing to keep its premises in reasonable repair and suitable for the uses to which they were being put;

k. failing to recall said steroids in a timely manner;

l. failing to otherwise exercise reasonable care in the production and manufacture of steroids.

93. Defendants knew or should have known that their wrongful acts and omissions would injure individuals, including Plaintiff who had prednisone administered in a foreseeable manner.

94. As a direct and proximate result of the acts and omissions of Defendants, Plaintiff suffered serious, permanent, and disabling injuries, pain and suffering, disability, disfigurement, mental anguish; aggravation of a previously existing injury, disease or condition; loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and loss of earnings and ability to earn money. These losses are permanent and continuing in nature and Plaintiff will continue to suffer these losses in the future.

WHEREFORE, Plaintiff Vilinda York requests that the Court enter judgment in her favor and against the Defendants awarding compensatory damages, costs, post judgment interest, and any and all such further relief that the Court deems just and proper.

COUNT II
OFFICER AND DIRECTOR LIABILITY OF NECC'S RELATED ENTITIES (THE INDIVIDUAL DEFENDANTS)

95. Plaintiff adopts and restates paragraphs 1-21 as if fully set forth herein.

96. Plaintiff incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

97. Each of the Individual Defendants directly participated in the production of the epidural steroidal medications in question and the management and oversight of the operations of NECC, also including the marketing and sale of its products; as such each individual Defendant is liable for their own negligent and grossly negligent acts, violation of statutes, and other conduct supporting the claims of Plaintiff as set forth herein and resulting in Plaintiff's injury.

98. Further, upon information and belief, Defendants, Barry Cadden, Lisa Cadden, Gregory Conigliaro, Douglas Conigliaro and Carla Coniglaro had knowledge of and acted to do the following in their capacity as directors and officers of Defendants:

a. violate state and federal laws by preparing and selling compounded medications, specifically epidural steroids, which "were not labeled with patient-specific identifiers, as is required under Massachusetts licensing regulations;"

b. failing to follow and enforce compounding/manufacturing standards regarding sterility and cleanliness such that the epidural steroid became contaminated with fungus, including, but not limited to Aspergillus fumigatus and Exserohilum rostratum. Such failures included, allowing floor mats that technicians and pharmacists were supposed to use before entering clean areas which were soiled with assorted debris, and permitting the presence of a leaky boiler next to a clean room that was supposed to maintain the highest barriers against contamination;

c. failing to follow and enforce compounding/manufacturing standards regarding sterility testing of product in that NECC's pharmacists did not allow "even the minimum amount of time" to confirm that a batch of medication was sterile before shipping it to health care providers, physicians, medical facilities and other care providers, including the clinic where Plaintiff received her injection;

d. acting to compound, market, sell and ship contaminated epidural steroid medications in Michigan, knowing that such actions did not meet minimum standards for patient safety and were in violation of state and federal laws.

99. As a consequence of these direct actions, Defendants Barry Cadden, Lisa Cadden, Gregory Conigliaro, Douglas Conigliaro and Carla Coniglaro are each individually liable for the injuries of Plaintiff as set forth herein.

100. As a direct and proximate result of the acts and omissions of Defendants, Plaintiff suffered serious, permanent, and disabling injuries, pain and suffering, disability, disfigurement, mental anguish; aggravation of a previously existing injury, disease or condition; loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and loss of earnings and ability to earn money. These losses are permanent and continuing in nature and Plaintiff will continue to suffer these losses in the future.

WHEREFORE, Plaintiff Vilinda York requests that the Court enter judgment in her favor and against the Defendants awarding compensatory damages, costs, post judgment interest, and any and all such further relief that the Court deems just and proper.

COUNT III
STRICT LIABILITY AGAINST NECC AND NECC'S RELATED ENTITIES (AMERIDOSE, MSM, MSM-SW, ARL, GDC AND THE INDIVIDUAL DEFENDANTS)

101. Plaintiff adopts and restates paragraphs 1-88 as if fully set forth herein.

102. The subject steroid was designed, manufactured, and placed in the stream of commerce by NECC and NECC Related Entities with the expectation that it would reach the ultimate user in the condition it was in when used by Plaintiff.

103. Defendants knew or should have known that the subject steroid would be used by Plaintiff, and the product in fact was used, without inspection for defects.

104. The subject steroid was defective and unreasonably dangerous in one or more of the ways discussed below.

105. The defective condition of the subject steroid rendered it in an unreasonably dangerous condition at the time it was placed into the stream of commerce by NECC and NECC Related Entities.

106. The subject steroid was in a defective and unreasonably dangerous condition at the time it left the possession and control of Defendants.

107. When the subject steroid was injected it was in substantially the same condition it was when Defendants manufactured, sold and/or delivered it.

108. At all times relevant thereto, the subject steroid was used in a manner consistent with the uses intended by or known to Defendants, and according with Defendants' directions and instructions.

109. Defendants also failed to adequately warn of the subject steroid's defects and is strictly liable to Plaintiff as a result of their failure to adequately warn the Plaintiff of the steroid's dangerous and hazardous state.

110. Defendants are strictly liable to Plaintiffs for their injuries.

111. As a direct and proximate result of the acts or omissions of Defendant, Plaintiff has in the past suffered and will in the future continue to suffer bodily injury, pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of ability to earn money, and aggravation of a pre-existing condition. These losses are permanent and continuing in nature and the Plaintiff will continue to suffer these losses in the future.

WHEREFORE, Plaintiff Vilinda York requests that the Court enter judgment in her favor

and against the Defendants awarding compensatory damages, costs, post judgment interest, and any and all such further relief that the Court deems just and proper.

COUNT IV
DECEPTIVE AND UNFAIR TRADE PRACTICES AGAINST NECC AND NECC'S RELATED ENTITIES (AMERIDOSE, MSM, MSM-SW, ARL, GDC AND THE INDIVIDUAL DEFENDANTS)

112. Plaintiff adopts and restates paragraphs 1-88 as if fully set forth herein.

113. This is an action for relief under section 501.201, *et.seq.,* Florida Statutes (The Florida Deceptive and Unfair Trade Practices Act).

114. Section 501.203(7), Florida Statutes defines "Consumer" as "an individual; child, by and through its parent or legal guardian; firm; association; joint venture; partnership; estate; trust; business trust; syndicate; fiduciary; corporation; or any other group or combination." Plaintiffs is a "Consumer" within the meaning of §501.203(7), Florida Statutes.

115. Section 501.203(8), Florida Statutes defines "Trade or Commerce" as:

> [T]he advertising, soliciting, providing, offering, or distributing, whether by sale, rental, or otherwise, of any good or service, or any property, whether tangible or intangible, or m1y other article, commodity, or thing of value, wherever situated. "Trade or Commerce" shall include the conduct person or activity.

116. The advertising, soliciting, providing, offering, or distributing of steroids by Defendants to Plaintiff is "Trade or Commerce" within the meaning of section 501.203(8), Florida Statutes.

117. Section 501.204(1) provides that: "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." The Defendants' acts and omissions as well as their failure to use reasonable care in

this matter as alleged in this Complaint equals unconscionable acts or practices, as well as deceptive and unfair acts or practices in the conduct of Defendants' trade or commerce pursuant to section 501.204, Florida Statutes.

118. The unconscionable, illegal, unfair and deceptive acts and practices of Defendants violate the provisions of Florida's Deceptive and Unfair Trade Practices Act. Plaintiff has suffered actual damage for which he is entitled to relief pursuant to section 501.211(2), Florida Statutes.

119. Plaintiff is entitled to recover reasonable attorneys' fees pursuant to section 501.2105, Florida Statutes upon prevailing in this matter.

120. As a direct and proximate cause of Defendants' acts and omissions, Plaintiffs have incurred actual damages and are entitled to recover actual damages for the dangerous steroid.

121. As a direct and proximate result of the acts and omissions of Defendants, Plaintiff suffered serious, permanent, and disabling injuries, pain and suffering, disability, disfigurement, mental anguish; aggravation of a previously existing injury, disease or condition; loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and loss of earnings and ability to earn money. These losses are permanent and continuing in nature and Plaintiff will continue to suffer these losses in the future.

WHEREFORE, Plaintiff Vilinda York requests that the Court enter judgment in her favor and against the Defendants awarding compensatory damages, costs, post judgment interest, and any and all such further relief that the Court deems just and proper.

COUNT V
NEGLIGENCE AGAINST LIBERTY INDUSTRIES, INC.

122. Plaintiff adopts and restates paragraphs 1-21 as if fully set forth herein.

123. Defendant Liberty Industries, Inc., owed a duty of reasonable care to Plaintiff to provide a reasonably safe steroid, free from contamination, and to adequately warn of its failure to do the same. Defendant's duty included, but was not limited to:

a. Properly performing due diligence in the design, construction, choice of materials and general building of the clean rooms at NECC.

b. Adequately testing, training, and developing procedures and materials used in the clean rooms at NECC.

c. adequately warning Plaintiff or the public regarding the likelihood of injury arising out of the use of its steroids, at the time of design, compound and post- compounding but prior to its injection into Plaintiff;

d. properly testing and inspecting its design, testing and production systems of its steroids, before placing them into the stream of commerce;

e. using alternative available production practices that would have prevented the contamination of its steroids without significantly impairing the product;

f. exercising reasonable care in making the design and production choices made by Defendants;

g. keeping premises in reasonable repair and suitable for the uses to which they were being put;

a. otherwise exercising reasonable care in the design and construction of the NECC clean rooms.

124. Defendant was negligent and breached its duty of reasonable care to Plaintiff to provide a reasonably safe steroid free of contamination and to adequately warn of their failure to do the same. Defendant's breaches included but were not limited to the following:

a. failing to perform due diligence in the design, construction, choice of materials and general building of the clean rooms at NECC;

b. failing to adequately test, train, and develop procedures and materials used in the clean rooms at NECC;

c. failing to adequately warn Plaintiff or the public regarding the likelihood of injury arising out of the use of its steroids, at the time of design, compound and post- compounding but prior to its injection into Plaintiff;

d. failing to properly test and inspect its design, testing and production systems of its steroids, before placing them into the stream of commerce;

e. failing to use alternative available production practices that would have prevented the contamination of its steroids without significantly impairing the product;

f. failing to exercise reasonable care in making the design and production choices made by Defendants;

g. failing to keep premises in reasonable repair and suitable for the uses to which they were being put;

a. failing to otherwise exercise reasonable care in the design and construction of the NECC clean rooms.

125. Defendants knew or should have known that their wrongful acts and omissions would injury individuals, including Plaintiff who had prednisone administered in a foreseeable manner.

126. As a direct and proximate result of the acts and omissions of Defendants, Plaintiff suffered serious, permanent, and disabling injuries, pain and suffering, disability, disfigurement,

mental anguish; aggravation of a previously existing injury, disease or condition; loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and loss of earnings and ability to earn money. These losses are permanent and continuing in nature and Plaintiff will continue to suffer these losses in the future.

WHEREFORE, Plaintiff Vilinda York requests that the Court enter judgment in her favor and against the Defendants awarding compensatory damages, costs, post judgment interest, and any and all such further relief that the Court deems just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury of all issues so triable as a matter of right.

Dated: January 28, 2014.

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